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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/710,181

11/10/2000

Steven D. Jensen

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7590

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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT

PAPER NUMBER

1616

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/710,181	Applicant(s) JENSEN ET AL.	
	Examiner ALTON N. PRYOR	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41,42,44-48,50-87 and 91-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41,42,44-48,50-87 and 91-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 12/8/08 have been fully considered but they are not persuasive. See argument below. Previous rejections not addressed below are withdrawn.

On papers filed 12/8/08 Applicants list serial number 07/710,181. Please correct application serial number. Applicants filed an IDS after the submission of Appeal Brief. This action by the Applicants caused the return of the file to the Examiner without a Board decision.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin (USPN 6108850;8/29/00) and Shimada et al (USPN 5626837; 5/6/97). McLaughlin teaches a composition for whitening teeth comprising a bleaching agent such as 10% hydrogen peroxide and an agent for reducing tooth sensitivity such as 1% potassium nitrate. See column 4 lines 5-12, column 7 Example 4. McLaughlin suggests bleaching agents other than hydrogen peroxide (e.g. 10 to 40% carbamide peroxide or carbamyl peroxide) can be used in the composition. See column 2 line 15 – column 3 line 7. McLaughlin suggests that the composition can further comprise water, polyethylene glycol (see column 2 line 64 – column 3 line 7), xanthan gum (column 3 lines 38—61) and stannous fluoride (column 3 line 62 - column 4 line 4). McLaughlin teaches a method of applying the composition to teeth for the purpose of whitening teeth. McLaughlin teaches that the composition can be

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applied using a dental tray. See column 4 line 59 - column 5 line 15. McLaughlin teaches all that is recited in claims 52,54 and 74-76 except for the invention comprising an antimicrobial agent such as cetyl pyridinium bromide and stabilizer such as citric acid as well as the length of time the teeth are subjected to dental tray application. However, Shimada et al teach dental compositions (toothpaste, mouthwash, etc.) comprising antimicrobial agents such as cetyl pyridinium chloride, pH adjustors such as citric acid, actives such as stannous fluoride and humectants such as polyethylene glycol (see abstract, column 1 lines 17- 42, column 3 line 57 – column 4 line 31). It would have been obvious to one having ordinary skill in the art to modify the invention of McLaughlin to include the cetyl pyridinium halide and the citric acid taught by Shimada et al. One would have been motivated to do this since both inventions are to dental / oral compositions for the protection and healthy maintenance of teeth. In addition one would have been motivated to do this in order to protect the teeth and gums from bacterial infection, and one would have been motivated to employ citric acid in order to adjust the pH of the composition to a stable environment. With respect to the time length of applying the dental tray to the teeth, one having ordinary skill in the art would have been motivated to determine the optimum time range in order to obtain the best result of whitening and protecting teeth.

Response to Applicants' Argument

The Applicants amended claims to recite the composition comprising about 3% to about 30% bleaching agent which is narrower than the original range of about 0.5 to about 50% bleaching agent. The Applicants argue that tested compositions comprising 10.5 and 15% bleaching agent show unexpected results that would represent the amended range of about 3 to about 30% bleaching agent. The Applicants argue that the further amended range in the claims of

about 10 to about 20% is even better tailored than the tested compositions comprising 10.5 and 15 % bleaching agent.

The Examiner argues that the bleaching agent appears to be the key element for the invention. The Examiner maintains that the Applicants' results provided for compositions comprising 10.5 and 15 % bleaching agents would not represent the broad range of about 3% to about 30% bleaching agent since McLaughlin teaches a composition comprising 10% bleaching agent and 1% potassium nitrate. This teaching of McLaughlin also reads on the claimed composition comprising 10 to 20 % bleaching agent.

The Applicants argue that McLaughlin's Example 4 discloses a toothpaste comprising hydrogen peroxide and potassium, but no identifiable solvent or tackifying agent. The Applicants further argues that the combination of McLaughlin and Shimada et al. does not, without hindsight, suggest the combination of elements recited in claim 41 as amended.

The Examiner argues that McLaughlin only exemplifies a toothpaste. However, McLaughlin teaches that the disclosed and suggested composition can be used in a dental tray that can be applied to teeth (column 4 line 59 – column 5 line 15). McLaughlin also teaches that the disclosed and suggested composition therein may comprise solvents and tackifying agent (column 3 lines 38-61).

The term toothpaste denotes an abrasive composition used to clean teeth when brushing. McLaughlin does not teach or suggest a dental formulation comprising a dental bleaching agent in the claimed amount and a carrier that contains a solvent and a tackifying agent to yield a bleaching composition free of abrasives.

While this is true, many of the claims do not state the instant composition is free of abrasives. Note, claims 55,64 and 69 exclude abrasives from the instant composition and these claims would be allowable once added to the independent claims.

Claim 86 has been amended to recite a stable, one part composition, whereas McLaughlin teaches a two-part composition that includes a separate catalyst for mixing with an intermediate bleaching compound. The composition of claim 86 is sticky and viscous by virtue of including a sticky, viscous carrier into which the bleaching agent and potassium nitrated are dispersed. There exist no indications that McLaughlin produces sticky and viscous compositions that can place in a dental bleaching tray to be applied to teeth.

The Examiner argues that no where in McLaughlin is it stated that the composition is a two-part composition and no where in the instant specification is it recited that the composition is a stable, one part composition. Both instant invention and McLaughlin's invention suggest the same combination of ingredients; therefore, it is obvious that the two inventions would produce compositions having the similar characteristics (sticky and viscous).

The method steps in claims 72-85 are not suggested or taught by McLaughlin. The step of contacting a person's teeth with the dental bleaching composition (without scrubbing or brushing) for a sufficient time to bleach teeth is not taught by McLaughlin.

The Examiner argues that McLaughlin teaches that the disclosed and suggested composition can be used in a dental tray to be applied to teeth (column 4 line 59 – column 5 line 15). Such an application would not involve brushing or scrubbing the teeth.

Applicant argues that the only Example in McLaughlin includes a bleaching agent and potassium nitrate and the potassium nitrate is in an amount of 1%. As shown by Applicant in a

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comparative study, dental bleaching compositions that include 0.5% potassium nitrate provide the best reduction in sensitivity. The Examiner argues that the instant claims are broader in scope than the examples showing unexpected results provided by the Applicants. Applicants provide unexpected results for an invention comprising 0.5% potassium nitrate and 10.5% or 15% carbamide peroxide.

Claims 41,42,44-48,50-87,91-93 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6306370. Although the conflicting claims are not identical, they are not patentably distinct from each other because Fischer (USPN 6306370) claims a composition comprising 3-20 % peroxides such as carbamide peroxide and hydrogen peroxide plus 0.1-10 % potassium nitrate. The composition can further comprise carboxypolymethylene, polyols such as glycerine, up to 50 % water, active agents such as sodium fluoride and tetracycline, and stability enhancers such as EDTA. Fischer's invention (USPN 6306370) also claims a method to whitening (bleaching) teeth with the composition with the aid of a tray. Fischer's invention (USPN 6306370) discloses amounts of potassium nitrate (0.1-10 %) and peroxide (3-20 %), which encompass instant amounts of potassium nitrate and peroxide. Fischer's invention (USPN 6306370) also claims a method to bleaching teeth with the composition with the aid of a tray. For this reason, it would have been obvious to one having ordinary skill in the art at the time the invention (USPN 6306370) was made to employ the instant amounts of potassium nitrate and peroxide. One would have been motivated to do this since the USPN 6306307 amounts overlap the instant amounts. Applicant points out in a declaration and a working example that 10.5 % and 15 % carbamide plus 0.5 % potassium nitrate yields unexpected data. Applicant also refers Examiner to examples

3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, the Examiner argues that the declaration is not commensurate in scope with claims because the claims recite a range of 3-30% peroxide and applicants' declaration only shows results for ranges of peroxide being 10% or 15%. In the previous rejection mailed 4/16/08, the Examiner inadvertently left claims 72-86 out of the 103(a) rejection. Note it is obvious that the Examiner intended to include claims 72-86 in the rejection since the prior art cited suggests the combination of potassium nitrate, bleaching agent, solvent and tackifying agent as described in the office action mailed 4/16/08.

Response to Applicants Argument

Rejection of claims 41,42,44-48,50-87,91- 93 over obviousness-type double patenting with respect to USPN 6306370 will be maintained for reason on record and reason as follows.

Applicants make several arguments as to why the rejection should be withdrawn. Applicants provide declarations to support their position. Applicants also point out that a double patenting rejection is over the claims not the body of the disclosure.

The Examiner agrees with the point made by the Applicants that a double patenting rejection is over the claims not the body of the disclosure. It is for that very reason the double rejection over USPN '370 is maintained.

- A) Note that Applicants' claims are to a dental bleaching composition comprising:
- 1) about 10 to about 30 % peroxide as to have a tooth bleaching effect;
 - 2) about 0.05 to about 1 % potassium nitrate as to result in reduced tooth sensitivity that may be caused by the peroxide; and
 - 3) a carrier.

B) Note that USPN '370 makes claim (see claim 14) to a dental bleaching composition comprising:

- 1) about 3 to about 20% peroxide;
- 2) about 0.01 to about 10% potassium nitrate in an amount to reduce tooth sensitivity that may be caused by the peroxide; and
- 3) a carrier.

In the comparison of Applicants' claims with USPN '370 claims, the claims in USPN '370 makes obvious instant claims. Note instant claims to composition comprising about 10% to about 30 % peroxide overlaps USPN's peroxide range of about 3% to about 20% peroxide. Note that instant claims to composition comprising about 0.05 to about 1 % potassium nitrate fall within the range (about 0.01 to about 10%) claimed in USPN '370. Therefore, USPN '370 claims makes obvious the instant claims. Applicants provide unexpected for a composition comprising 10 or 15 % peroxide and 0.5 % potassium nitrate (see evidence appendix). As recited in office action of 4/5/2005, the Examiner agrees that results are convincing as well as unexpected. However, the Examiner maintains that the claims are not commensurate in scope with the examples tested. For this reason, the rejection is maintained. Applicants argue that the criticality of the invention lies within the amount of potassium nitrate not in the amount of peroxide. This may be true, however, this statement is not convincing since Applicants only provide data for 10% and 15% peroxide in the broad range of about 3 to about 30% peroxide instantly claimed. For the above reasons USPN '370 is cited as an obviousness-type double patenting rejection over instant claims.

The Examiner further argues that Applicants' data provided in paper filed 12/15/04 show that sensitivity is reduced by a composition comprising carbamide peroxide and 0.5% potassium nitrate. The problem with the data is that the concentration of carbamide peroxide is not provided. Without the concentration of carbamide peroxide, the applicants' amendments to the claims do not overcome the obviousness type double patenting rejection. The claims are not commensurate in scope with data provided in paper filed 12/15/04. The claimed ranges of 0.05 - 1 % potassium nitrate and 10 - 30% carbamide peroxide are not commensurate in scope with the unexpected results since the only data point tested using potassium nitrate was at 0.5% potassium nitrate and the only data points tested using carbamide peroxide were at 10.5% and 15% carbamide peroxide.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "without brushing" is new matter.

Claims 41,42,44-48,50-87,91-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrases "non-abrasive" and "non-abrasive gel" are new matter phrases.

Other New Matter issues are regarding percentages below:

"*about* 10%" bleaching agent in claims 41,45,72,77,81, 86 and 91-93;

"*about* 15%" bleaching agent in claims 45,91 and 92;

"*about* 0.5%" potassium nitrate in claims 46,61,65 and 81.

Please correct or explain new matter issues. If similar percentage new matter issues are raised in subsequent rejection, the rejection may be cited as final. Please check percentage new matter issues very carefully.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTON N. PRYOR whose telephone number is (571)272-0621.

The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/

Primary Examiner, Art Unit 1616